FORM PTO-1390 (REV 11-98) — U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
4278/PCT	
US APPLICATION NO (If known, see 37 CFR 1.5)	
(unknown)	10/049,703
INTERNATIONAL APPLICATION NO	INTERNATIONAL FILING DATE
PCT/DE00/03310	22. September, 2000 (22.09.00)
PRIORITY DATE CLAIMED	
23. September 1999 (23.09.99)	

TITLE OF INVENTION: Method and Device for Inserting Implants Into Human Organs

APPLICANT(S) FOR DO/EO/US: Oliver ROEHE; Horst LAUBE; Martin MATTHAEUS

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1)
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [X] A translation of the International Application into English (35 U.S.C. 371(c)(2)), with Translator's Declaration.
7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired
   d. [X] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. [X] An Information Disclosure Statement under 37 CFR 1.97 and 1.98, Form PTO-1449, 2 references.
12. [X] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment, to minimize the filing fee.
    [X] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information:
    a. a return receipt postcard;
    b. Form PTO-2038 (Credit Card Payment Form);
    c. 6 Figs. on 2 sheets of drawings;
    d. copy of International Search Report (and English version thereof)
    e) **marked-up version of Spec. Pgs. 1-5, 8.**

NOTE: The priority of German Patent Application 199 45 587.2, filed in the Federal Republic of Germany on September 23, 1999 is claimed under 35 U.S.C. §119.

NOTE: This application has been assigned to: **co.don AG**
of: Warthestr. 21
D-14513 Teltow
Federal Republic of Germany

The Assignment is being submitted for recordal.

USPS EXPRESS MAIL
EV 059 670 853 US
FEBRUARY 14 2002

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
(unknown) 10/049203	PCT/DE00/03310	4278/PCT

	CALCULATIONS	PTO USE ONLY
17 [X] The following fees are submitted:		
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO	~~XXXXXX~~	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	$890.00 ~~XXXXXX~~	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO	~~XXXXXX~~	
International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4)	~~XXXXXX~~	
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4)	~~XXXXXX~~	
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 890.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 0	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	23 - 20 =	3	X $18.00	$ 54.00	
Independent claims	3 - 3 =	0	X $78.00	$ 0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $260.00	$ 0	
TOTAL OF ABOVE CALCULATIONS =				$ 944.00	
Reduction of 1/2 for filing by small entity, if applicable. A Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				$ 0	
SUBTOTAL =				$944.00	
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)) +				$ 0	
TOTAL NATIONAL FEE =				$944.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property +				$ 40.00	
TOTAL FEES ENCLOSED =				$984.00	
				Amount to be: refunded	$
				charged	$

a. [X] Form PTO-2038 (Credit Card Payment Form) ~~XXXXX~~ in the amount of $ $984.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0507 . ~~A duplicate copy of this sheet is enclosed.~~

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO
CUSTOMER NO.: 021553

USPS EXPRESS MAIL
EV 059 670 853 US
FEBRUARY 14 2002

Walter F. Fasse
SIGNATURE

Walter F. Fasse 2/14/02
NAME

36132
REGISTRATION NUMBER

DOCKET NO.: 4278/PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE MATTER OF THE **PCT NATIONAL PHASE PATENT APPLICATION**

OF: Oliver ROEHE et al.

USSN: TO BE ASSIGNED - NEW

FILED: February 14, 2002

FOR: Method and Device for Inserting Implants Into Human Organs

INTERNATIONAL SERIAL NO.: PCT/DE00/03310
INTERNATIONAL FILING DATE: 22. September, 2000 (22.09.00)

ASSISTANT COMMISSIONER FOR PATENTS
BOX PCT
WASHINGTON, D. C. 20231

February 14, 2002

FIRST PRELIMINARY AMENDMENT TO MINIMIZE THE FILING FEE

Dear Sir:

In order to minimize the filing fee, please amend the above identified patent application as follows before calculating the filing fee.

Referring to the Literal Translation of International Application PCT/DE00/03310

In the Claims:

Claims **1** and **2** are maintained for calculating the filing fee. Please cancel claims **3** to **8**.

REMARKS:

After calculating the filing fee, please further enter the accompanying Second Preliminary Amendment which introduces new claims **9 to 31** for examination.

Respectfully submitted,

Oliver ROEHE et al.
Applicant,

By

Walter F. Fasse
Patent Attorney
Reg. No.: 36132
Tel. No.: (207) 862-4671
Fax. No.: (207) 862-4681
P. O. Box 726
Hampden, ME 04444-0726

WFF:ar/4278/PCT
Encls.: postcard
USPS EXPRESS MAIL
EV 059 670 853 US
FEBRUARY 14 2002

DOCKET NO.: 4278/PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE MATTER OF THE **PCT NATIONAL PHASE PATENT APPLICATION**

OF: Oliver ROEHE et al.

USSN: TO BE ASSIGNED - NEW

FILED: February 14, 2002

USPS EXPRESS MAIL
EV 059 670 853 US
FEBRUARY 14 2002

FOR: Method and Device for Inserting Implants Into Human Organs

INTERNATIONAL SERIAL NO.: PCT/DE00/03310
INTERNATIONAL FILING DATE: 22. SEPTEMBER, 2000 (22.09.00)

ASSISTANT COMMISSIONER FOR PATENTS
BOX PCT
WASHINGTON, D. C. 20231

February 14, 2002

SECOND PRELIMINARY AMENDMENT

Dear Sir:

After calculating the filing fee, but before the first examination, please amend the above identified application as follows.

Referring to the Literal Translation of International Application PCT/DE00/03310

In the Specification:

Please delete and replace the heading at **page 1, above line 1,** to read as follows:

TITLE OF THE INVENTION

Please insert a new heading at **page 1, following line 1 and above line 2**, to read as follows:

FIELD OF THE INVENTION

Please insert a new heading at **page 1, following line 5 and above line 6**, to read as follows:

BACKGROUND INFORMATION

Please delete and replace the paragraph at **page 1, lines 6 to 16**, to read as follows:

In order to prevent, or at least reduce to a minimum, the immune reaction of the human organism with respect to implanted organ parts which are foreign to the body, and in order to prolong the long term durability or service life of special biological implants, it is an already known measure to coat the surfaces of the implants with living cells before the implantation into the human organism. Ideally, homologous cells, i.e. the body's own cells, or cells identical thereto, are concerned in this context. In that regard, the coating of the implants can be carried out in an especially advantageous manner in an apparatus as is described in the German Patent 198 34 396 C1 and corresponding U. S. Patent 6,214,407.

Please insert a heading at **page 2, following line 6, and above line 7** to read as follows:

SUMMARY OF THE INVENTION

Please delete and replace the paragraph at **page 3, lines 5 to 22**, to read as follows:

Therewith the invention has the advantage, that the elements that are to be connected with one another cannot be loosened or released from one another in an automatic or self-acting manner, also in connection with a pulsating internal pressure, as it exists in connection with the heart. By means of elastic seal edges, a sufficient seal to the inside and to the outside is ensured simultaneously. On the other hand, a loosening or releasing of the connection is also still possible after several years of installed use, as the case may be, with the aid of a specially fitted disassembly tool. Thereby it is possible to fabricate the adapter element as well as the receiver element of a sterilizable body-compatible synthetic material. Finally, the adapter element provided in the apparatus according to the invention has the advantage that it can, without problems, be coated with living cells, together with the organ part that is to be implanted, preferably a biological as well as artificial heart valve, in the apparatus described in the German Patent 198 34 396 C1 and the corresponding U. S. Patent 6,214,407.

Please insert a heading at **page 3, following line 22 and above line 23**, to read as follows:

BRIEF DESCRIPTION OF THE DRAWINGS

Please insert a heading at page 4, **following line 11 and above line 12**, to read as follows:

DETAILED DESCRIPTION OF A PREFERRED EXAMPLE EMBODIMENT OF THE INVENTION

In the Claims:

Please cancel Claims **1** and **2**.

Claims **3 to 8** have previously been cancelled in applicants' First Preliminary Amendment.

Please enter new claims **9 to 31** as follows.

9. (new) A system for inserting an implant into a human organ comprising:

an adapter element comprising a ring-shaped adapter body and an annular adapter flange projecting from said adapter body; and

a receiver element comprising a ring-shaped receiver body and an annular receiver flange projecting from said receiver body;

wherein:

said adapter element is adapted to be connected to an implant, said receiver element is adapted to be connected to a human organ, and said adapter element and said receiver element are adapted to be connected to each other.

10. (new) The system according to claim 9, wherein said adapter flange is adapted to be connected to the implant, said receiver flange is adapted to be connected to the human organ, and said adapter body and said receiver body are adapted to be connected to each other.

11. (new) The system according to claim 10, wherein said receiver body has an external threading.

12. (new) The system according to claim 11, wherein said adapter body has an internal threading adapted to mate with said external threading of said receiver body.

13. (new) The system according to claim 12, wherein said internal threading and said external threading are each respectively provided with mutually cooperating self-locking guide parts.

14. (new) The system according to claim 12, wherein said receiver flange projects radially outwardly from said receiver body and said adapter flange projects radially inwardly from said adapter body.

15. (new) The system according to claim 10, wherein said receiver flange projects radially outwardly from said receiver body and said adapter flange projects radially inwardly from said adapter body.

16. (new) The system according to claim 10, wherein said adapter body has an internal threading adapted to mate with said external threading of said receiver body.

17. (new) The system according to claim 10, wherein said adapter body and said receiver body are respectively provided with interengaging bayonet lock fastener components.

18. (new) The system according to claim 10, wherein said adapter flange has first elements adapted to receive a suture to connect said adapter flange to the implant, and said receiver flange has second elements adapted to receive a suture to connect said receiver flange to the human organ.

19. (new) The system according to claim 18, wherein said first elements are first throughholes in said adapter flange and said second elements are second throughholes in said receiver flange.

20. (new) The system according to claim 10, further comprising said implant, a first suture connecting said adapter flange to said implant, and a second suture connecting said receiver flange to the human organ.

21. (new) The system according to clam 20, further comprising a coating layer of living cells covering a surface of said implant and a surface of said adapter element.

22. (new) The system according to claim 20, wherein said implant is a biological heart valve.

23. (new) The system according to claim 20, wherein said implant is an artificial heart valve.

24. (new) A system for inserting an implant into a human organ, comprising:

an implant;

an adapter element comprising a ring-shaped adapter body and an annular adapter flange projecting radially from said adapter body;

a first suture connecting said adapter flange to said implant;

a receiver element comprising a ring-shaped receiver body that is dimensioned and adapted to mate with and releasably connect with said adapter body, and an annular receiver flange that projects radially from said receiver body and is adapted to be connected to a human organ; and

a second suture adapted to connect said receiver flange to the human organ.

25. (new) The system according to claim 24, further comprising an integral coating layer of living cells continuously integrally covering a surface of said implant and an adjoining surface of said adapter element.

26. (new) The system according to claim 24, wherein said adapter body has a first threading, said receiver body has a second threading, and said first and second threadings

are configured and adapted to be threadingly engaged with each other to releasably connect said receiver body with said adapter body.

27. (new) A method of inserting an implant into a human organ, comprising the steps:

a) providing an implant;

b) connecting said implant to an adapter element;

c) suturing a receiver element to a human organ; and

d) connecting said adapter element, with said implant connected thereto, to said receiver element.

28. (new) The method according to claim 27, wherein said connecting of said adapter element to said receiver element comprises rotating said adapter element relative to said receiver element.

29. (new) The method according to claim 28, wherein said receiver element and said adapter element respectively include first and second threadings, and said rotating of said adapter element relative to said receiver element comprises engaging and screwing together said first and second threadings.

30. (new) The method according to claim 28, wherein said receiver element and said adapter element respectively include bayonet lock fastener components, and said rotating

of said adapter element relative to said receiver element comprises engaging and locking together said bayonet lock fastener components.

31. (new) The method according to claim 27, further comprising an additional step, performed after said step b) and before said step d), of coating a surface of said adapter element and of said implant connected to said adapter element with a coating layer of living cells.

In the Abstract:

Please delete and replace the heading and paragraph at **page 8, lines 1 to 17**, to read as follows:

ABSTRACT OF THE DISCLOSURE

In a method for inserting an implant, such as a biological or artificial heart valve into a human organ, first the implant is provided with an adapter element, then a receiver element that is adapted to fit the adapter element is sutured to the recipient organ, and finally the adapter element is connected to the receiver element. The receiver element and the adapter element are each ring-shaped and are provided with matched interengageable threadings. They are connected with one another by relative rotation via a self-locking bayonet lock. Before being connected to the receiver element, the implant together with the adapter element are coated with living cells. Both the receiver

element and the adapter element respectively have flanges that include elements for being sutured together with the recipient organ or the implant.

REMARKS:

1) The original specification was a literal translation of the PCT International Application. The specification has now been amended for better conformance with typical U. S. format. All of the amendments are supported by the substance and the context of the original disclosure, and no new matter has been added. A marked-up version of the amended portions of the specification is enclosed. Please enter these amendments.

2) The literally translated PCT claims 1 to 8 have been replaced by new claims 9 to 31, which have been drafted "from the ground up" in consideration of typical U. S. form, style and practice. The new claims 9 to 31 are based on the features of the original claims and the original description, and do not include any new matter. Examination of the present U. S. National Phase Application is to proceed on the basis of the new claims 9 to 31.

3) Favorable consideration and allowance of claims 9 to 31 are respectfully requested.

Respectfully submitted,

Oliver ROEHE et al.
Applicant

By _____
Walter F. Fasse
Patent Attorney
Reg. No.: 36132
Tel. No.: (207) 862-4671
Fax. No.: (207) 862-4681
P. O. Box 726
Hampden, ME 04444-0726

WFF:ar/4278/PCT
Encls.: postcard

USPS EXPRESS MAIL
EV 059 670 853 US
FEBRUARY 14 2002

10/049703
JC11 Rec'd PCT/PTO 14 FEB 2002

"MARKED-UP VERSION"

DOCKET NO: 4278/PCT
INVENTORS: Oliver ROEHE
Horst LAUBE
Martin MATTHAEUS

LITERAL TRANSLATION OF PCT INTERNATIONAL APPLICATION PCT/DE00/03310 AS FILED ON SEPTEMBER 22, 2000

TITLE OF THE INVENTION

Method and Device for Inserting Implants Into Human Organs

FIELD OF THE INVENTION

The invention relates to a method for the insertion of implants into human organs, especially for the installation of biological as well as artificial heart valves, as well as an apparatus for carrying out a method of this kind.

BACKGROUND INFORMATION

In order to prevent, or at least reduce to a minimum, the immune reaction of the human organism with respect to implanted organ parts which are foreign to the body, and in order to prolong the long term durability or service life of special biological implants, it is an already known measure to coat the surfaces of the implants with living cells before the implantation into the human organism. Ideally, homologous cells, i.e. the body's own cells, or cells identical thereto, are concerned in this context. In that regard, the coating of the implants can be carried out in an especially advantageous manner in an apparatus as is described in the German Patent 198 34 396 C1[] and corresponding U.S. Patent 6,214,407.

In any event, it is important in this procedure, that the vital cell layer of the thusly prepared organ parts, which are especially biological as well as synthetic or artificial heart

USPS EXPRESS MAIL
EV 059 670 853 US
FEBRUARY 14 2002

valves, is not destroyed by the surgical implantation technique, or are implanted into the human body, in this case into the recipient heart, in the shortest possible operation time after the completed coating, so that the applied cells do not already begin to die off before the successful completion of the transplantation.

SUMMARY OF THE INVENTION

An object of the invention is to develop a method of the above initially described type in such a manner so that it is ensured that artificial or biological organ parts, especially those that have been subjected to a cell coating before the implantation, can be inserted into the recipient organ in a short time and in an irritation-free manner to the extent possible. Moreover, it is an object of the invention, to provide an apparatus for carrying out a method of this type.

The invention achieves the first object by a method in which the implant is provided with an adapter element, a receiver element adapted or matched to the adapter element is sutured together with the recipient organ, and the adapter element is connected with the receiver element. The further object is achieved according to the invention by an apparatus, in which both the receiver element as well as the adapter element are embodied with a ring shape and are respectively provided with a flange-like shoulder or projection.

In an advantageous further development of the invention, it is provided in this context, that the connection of adapter element

and receiver element is achieved via a fastener, that is embodied as a bayonet lock and essentially only requires a rotation or turning. Moreover, this fastener is equipped with self-locking guide elements in an advantageous embodiment of the invention.

Therewith the invention has the advantage, that the elements that are to be connected with one another cannot be loosened or released from one another in an automatic or self-acting manner, also in connection with a pulsating internal pressure, as it exists in connection with the heart. By means of elastic seal edges, a sufficient seal to the inside and to the outside is ensured simultaneously. On the other hand, a loosening or releasing of the connection is also still possible after several years of installed use, as the case may be, with the aid of a specially fitted disassembly tool. Thereby it is possible to fabricate the adapter element as well as the receiver element of a sterilizable body-compatible synthetic material. Finally, the adapter element provided in the apparatus according to the invention has the advantage that it can, without problems, be coated with living cells, together with the organ part that is to be implanted, preferably a biological as well as artificial heart valve, in the apparatus described in the German Patent 198 34 396 C1[,] and the corresponding U.S. Patent 6,214,407.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following, the invention shall be described in further detail in connection with an example embodiment illustrated as a general principle in the drawing. Therein:

Fig. 1 shows a top plan view onto a receiver element,

Fig. 2 shows the element according to Fig. 1 in a partially sectioned side illustration,

Fig. 3 shows an enlarged detail illustration III of the arrangement according to Fig. 2,

Fig. 4 shows a partially sectioned side illustration of an adapter element,

Fig. 5 shows an enlarged detail illustration V of the arrangement according to Fig. 4, and

Fig. 6 shows an enlarged detail illustration of the threading in the screwed-together position.

DETAILED DESCRIPTION OF A PREFERRED EXAMPLE EMBODIMENT OF THE INVENTION

The receiver element 1 illustrated in the Figures 1 to 3 essentially consists of a ring that is provided with a flange-like shoulder or projection 2 and that has a threading 3 on its outer surface. In the presently illustrated example embodiment, in which the receiver element 1 serves for the implantation of an artificial heart valve, this ring, with an outer diameter of 29 mm and a width of about 3 mm, comprises a four-fold sharp V-thread with a pitch of 8 mm and a web width of 1 mm. In the presently illustrated example embodiment, the web height amounts to 0.5 mm. The flange 2 is provided with a set of bored through holes 4, which comprise a diameter of 0.4 mm in the presently

illustrated example embodiment, and which serve for the suturing with the recipient organ, in this case the recipient heart.

The adapter element 5 illustrated in the Figures 4 and 5 is similarly embodied as a ring with a flange-like shoulder or projection 6, whereby the flange is again provided with bored holes 7. In its interior, the adapter element 5 is provided with an internal threading 8, of which the dimensions are adapted or matched to the external threading of the receiver element 1. Both elements 1 and 5 consist of a sterilizable body-compatible synthetic or plastic.

In connection with the insertion of an artificial heart valve, before the actual operation, this valve is first connected with the adapter element 5, in this case being sutured together, and together with the adapter element is coated on the surface with living cells in an apparatus especially embodied for this purpose. Then, for beginning the transplantation operation, first the receiver element 1 is sutured into the heart, and in the following step the coated combination of heart valve and adapter element 5 is inserted into the receiver element 1, and both components are mechanically securely connected with one another by relative rotation or turning by about 30 angular degrees.

ABSTRACT OF THE DISCLOSURE

In a method for the insertion of implants into human organs, especially for the implantation of biological as well as artificial heart valves, first the implant is provided with an adapter element, then a receiver element that is matched or adapted to the adapter element is sutured to the recipient organ, and finally the adapter element is connected with the receiver element. Receiver element and adapter element are embodied with a ring shape and are provided with threadings that are matched to one another. They are connected with one another by turning or rotation via a self-locking bayonet lock. Before the connection with the receiver element, the implant together with the adapter element are coated with living cells. Both the receiver element as well as the adapter element are respectively provided with flange-like projections which, on their part, comprise constructive elements for suturing together with the recipient organ or the implant.

DOCKET NO: 4278/PCT
INVENTORS: Oliver ROEHE
Horst LAUBE
Martin MATTHAEUS

LITERAL TRANSLATION OF PCT INTERNATIONAL APPLICATION PCT/DE00/03310 AS FILED ON SEPTEMBER 22, 2000

Method and Device for Inserting Implants Into Human Organs

The invention relates to a method for the insertion of implants into human organs, especially for the installation of biological as well as artificial heart valves, as well as an apparatus for carrying out a method of this kind.

In order to prevent, or at least reduce to a minimum, the immune reaction of the human organism with respect to implanted organ parts which are foreign to the body, and in order to prolong the long term durability or service life of special biological implants, it is an already known measure to coat the surfaces of the implants with living cells before the implantation into the human organism. Ideally, homologous cells, i.e. the body's own cells, or cells identical thereto, are concerned in this context. In that regard, the coating of the implants can be carried out in an especially advantageous manner in an apparatus as is described in the German Patent 198 34 396 C1.

In any event, it is important in this procedure, that the vital cell layer of the thusly prepared organ parts, which are especially biological as well as synthetic or artificial heart

valves, is not destroyed by the surgical implantation technique, or are implanted into the human body, in this case into the recipient heart, in the shortest possible operation time after the completed coating, so that the applied cells do not already begin to die off before the successful completion of the transplantation.

An object of the invention is to develop a method of the above initially described type in such a manner so that it is ensured that artificial or biological organ parts, especially those that have been subjected to a cell coating before the implantation, can be inserted into the recipient organ in a short time and in an irritation-free manner to the extent possible. Moreover, it is an object of the invention, to provide an apparatus for carrying out a method of this type.

The invention achieves the first object by a method in which the implant is provided with an adapter element, a receiver element adapted or matched to the adapter element is sutured together with the recipient organ, and the adapter element is connected with the receiver element. The further object is achieved according to the invention by an apparatus, in which both the receiver element as well as the adapter element are embodied with a ring shape and are respectively provided with a flange-like shoulder or projection.

In an advantageous further development of the invention, it is provided in this context, that the connection of adapter element

and receiver element is achieved via a fastener, that is embodied as a bayonet lock and essentially only requires a rotation or turning. Moreover, this fastener is equipped with self-locking guide elements in an advantageous embodiment of the invention.

Therewith the invention has the advantage, that the elements that are to be connected with one another cannot be loosened or released from one another in an automatic or self-acting manner, also in connection with a pulsating internal pressure, as it exists in connection with the heart. By means of elastic seal edges, a sufficient seal to the inside and to the outside is ensured simultaneously. On the other hand, a loosening or releasing of the connection is also still possible after several years of installed use, as the case may be, with the aid of a specially fitted disassembly tool. Thereby it is possible to fabricate the adapter element as well as the receiver element of a sterilizable body-compatible synthetic material. Finally, the adapter element provided in the apparatus according to the invention has the advantage that it can, without problems, be coated with living cells, together with the organ part that is to be implanted, preferably a biological as well as artificial heart valve, in the apparatus described in the German Patent 198 34 396 C1.

In the following, the invention shall be described in further detail in connection with an example embodiment illustrated as a general principle in the drawing. Therein:

Fig. 1 shows a top plan view onto a receiver element,

Fig. 2 shows the element according to Fig. 1 in a partially sectioned side illustration,

Fig. 3 shows an enlarged detail illustration III of the arrangement according to Fig. 2,

Fig. 4 shows a partially sectioned side illustration of an adapter element,

Fig. 5 shows an enlarged detail illustration V of the arrangement according to Fig. 4, and

Fig. 6 shows an enlarged detail illustration of the threading in the screwed-together position.

The receiver element 1 illustrated in the Figures 1 to 3 essentially consists of a ring that is provided with a flange-like shoulder or projection 2 and that has a threading 3 on its outer surface. In the presently illustrated example embodiment, in which the receiver element 1 serves for the implantation of an artificial heart valve, this ring, with an outer diameter of 29 mm and a width of about 3 mm, comprises a four-fold sharp V-thread with a pitch of 8 mm and a web width of 1 mm. In the presently illustrated example embodiment, the web height amounts to 0.5 mm. The flange 2 is provided with a set of bored through holes 4, which comprise a diameter of 0.4 mm in the presently

illustrated example embodiment, and which serve for the suturing with the recipient organ, in this case the recipient heart.

The adapter element 5 illustrated in the Figures 4 and 5 is similarly embodied as a ring with a flange-like shoulder or projection 6, whereby the flange is again provided with bored holes 7. In its interior, the adapter element 5 is provided with an internal threading 8, of which the dimensions are adapted or matched to the external threading of the receiver element 1. Both elements 1 and 5 consist of a sterilizable body-compatible synthetic or plastic.

In connection with the insertion of an artificial heart valve, before the actual operation, this valve is first connected with the adapter element 5, in this case being sutured together, and together with the adapter element is coated on the surface with living cells in an apparatus especially embodied for this purpose. Then, for beginning the transplantation operation, first the receiver element 1 is sutured into the heart, and in the following step the coated combination of heart valve and adapter element 5 is inserted into the receiver element 1, and both components are mechanically securely connected with one another by relative rotation or turning by about 30 angular degrees.

Patent Claims:

1. Method for the insertion of implants in human organs, especially for the installation of biological as well as artificial heart valves, characterized in that the implant is provided with an adapter element (5), a receiver element (1) adapted to the adapter element (5) is sutured together with the recipient organ, and the adapter element (5) is connected with the receiver element (1).

2. Method according to claim 1, characterized in that the receiver element (1) and the adapter element (5) are provided with threadings (3, 8) adapted to each other, and are connected with each other by rotation, by means of a self-locking bayonet lock.

3. Method according to claim 1 or 2, characterized in that the implant together with the adapter element (5) is coated with living cells before the connecting with the receiver element (1).

4. Apparatus for carrying out the method according to one of the claims 1 to 3, characterized in that both the receiver element (1) as well as the adapter element (5) are embodied with a ring shape and are respectively provided with a flange-like projection (2, 6).

5. Apparatus according to claim 4, characterized in that the receiver element (1) is provided with an external threading (3).

6. Apparatus according to claim 4 or 5, characterized in that the adapter element (5) is provided with an internal threading (8).

7. Apparatus according to one of the claims 5 or 6, characterized in that the threadings (3, 8) of both the receiver element (1) as well as the adapter element (5) are provided with self-locking guide parts.

8. Apparatus according to one of the claims 4 to 7, characterized in that the flanges (2, 6) are provided with elements (4, 6) for suturing together with the recipient organ and the implant.

ABSTRACT

In a method for the insertion of implants into human organs, especially for the implantation of biological as well as artificial heart valves, first the implant is provided with an adapter element, then a receiver element that is matched or adapted to the adapter element is sutured to the recipient organ, and finally the adapter element is connected with the receiver element. Receiver element and adapter element are embodied with a ring shape and are provided with threadings that are matched to one another. They are connected with one another by turning or rotation via a self-locking bayonet lock. Before the connection with the receiver element, the implant together with the adapter element are coated with living cells. Both the receiver element as well as the adapter element are respectively provided with flange-like projections which, on their part, comprise constructive elements for suturing together with the recipient organ or the implant.

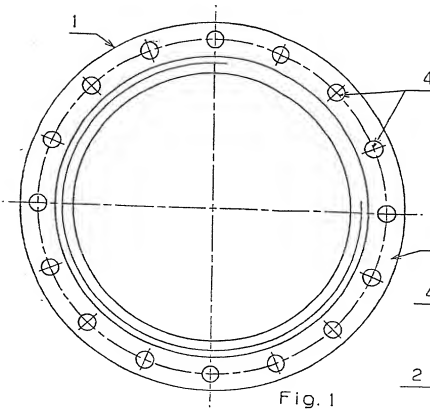

Fig. 1

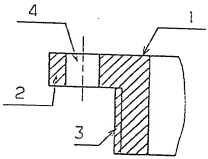

Fig. 3

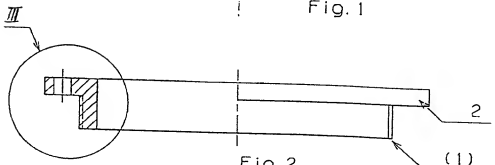

Fig. 2

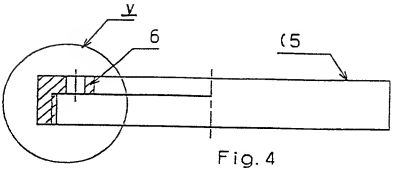

Fig. 4

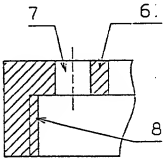

Fig. 5

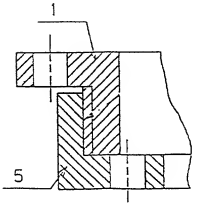

Fig. 6

Please type a plus sign (+) inside this box → [+]

PTO/SB/01 (10-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) WITH POWER OF ATTORNEY

☐ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	4278
First Named Inventor	Oliver ROEHE
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD AND DEVICE FOR INSERTING IMPLANTS INTO HUMAN ORGANS

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 09/22/2000 as United States Application Number or PCT International Application Number PCT/DE00/03310 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	Certified Copy Attached? NO
199 45 587.2	Fed. Rep. of Germany	09/23/1999	☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

our Case No.: 4278

Please type a plus sign (+) inside this box → [+]

PTO/SB/01 (10-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (if applicable)

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ☒ Customer Number 021553

Direct all correspondence to: ☒ Customer Number or Bar Code Label 021553

Place Customer Number Bar Code Label here

021553

PATENT AND TRADEMARK OFFICE

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]): Oliver
Family Name or Surname: ROEHE

Inventor's Signature: [signature] Date: 5th February, 2002

Residence: City 27721 Ritterhude State: DEX Fed. Rep. of Country Germany Citizenship German

Mailing Address: c/o CO.DON AG, Warthestr. 21

Mailing Address:

City Teltow State: ZIP 14513 Fed. Rep. of Country Germany

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]): Horst
Family Name or Surname: LAUBE

Inventor's Signature: [signature] Date: 5th February, 2002

Residence: City 10115 Berlin State: Fed. Rep. of Country Germany Citizenship German

Mailing Address: c/o CO.DON AG, Warthestr. 21

Mailing Address:

City Teltow State: ZIP 14513 Fed. Rep. of Country Germany

☐ Additional inventors are being named on the 3 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

Please type a plus sign (+) inside this box → [+]

PTO/SB/02A (10-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 3 of 3

3-00

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name: Martin		Family Name or Surname: MATTHAEUS	
Inventor's Signature: Martin Matthäus			Date: 5th February, 2002
Residence: City: 14052 Berlin	State:	Country: Fed. Rep. of Germany	Citizenship: German
Mailing Address: c/o CO.DON AG, Warthestr. 21			
Mailing Address:			
City: Teltow	State:	ZIP: 14513	Country: Fed. Rep. of Germany
Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name:		Family Name or Surname:	
Inventor's Signature:			Date:
Residence: City:	State:	Country:	Citizenship:
Mailing Address:			
Mailing Address:			
City:	State:	ZIP:	Country:
Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor		
Given Name:		Family Name or Surname:	
Inventor's Signature:			Date:
Residence: City:	State:	Country:	Citizenship:
Mailing Address:			
Mailing Address:			
City:	State:	ZIP:	Country: